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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/940,878	08/29/2001	Emmanuel Lazaridis	1372.61.PRCWOUS	5633
21901	7590	02/28/2006	EXAMINER	
SMITH & HOPEN PA 15950 BAY VISTA DRIVE SUITE 220 CLEARWATER, FL 33760			MILLER, MARINA I	
			ART UNIT	PAPER NUMBER
			1631	
DATE MAILED: 02/28/2006				

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/940,878

Applicant(s)

LAZARIDIS, EMMANUEL

Examiner

Marina Miller

Art Unit

1631

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 23 November 2005.  
2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.  
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-36 is/are pending in the application.  
4a) Of the above claim(s) 1-20 and 24-36 is/are withdrawn from consideration.  
5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.  
6) ☒ Claim(s) 21-23 is/are rejected.  
7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.  
8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.  
10) ☒ The drawing(s) filed on 11/23/2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)  
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)  
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_  
4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_  
5) ☐ Notice of Informal Patent Application (PTO-152)  
6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

Applicants' submission filed on 11/23/2005 is acknowledged.

Claims 1-36 are pending.

Claims 1-20 and 24-36 are withdrawn again from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected inventions and species, there being no allowable generic or linking claims.

An action on the merits of claims 21-23 as they read on the elected species, follows.

Applicants' arguments have been fully considered. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are applied.

#### ***Claim Rejections - 35 USC § 112***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim 21-23 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 21 recites the symbol " $\sigma^2$ ." Applicants argue that " $\sigma^2$ " is a well known in the field of statistical analysis to refer to the variance of a probability distribution. However, the same symbol is commonly used as a variance and as a parameter related to but not equivalent to the

Art Unit: 1631

square root of the variance, for example, in the log normal distribution, Maxwell distribution, and Rayleigh distribution. The symbol is not defined in either the claim or the specification, and therefore the intended limitation is not clear. Thus, claim 21 is indefinite, and the rejection is maintained.

Claim 22 comprises an expression  $N[\cdot]$ . The term " $N[\cdot]$ " is not recited in parent claim 21, therefore there is no antecedent basis for the term, and claim 22 is indefinite. Applicants argue that the symbol  $N[\cdot]$  is commonly used in statistics as a shorthand method for referencing a particular distribution without listing it. The examiner reviewed the prior art of record and other pertinent art, but did not find the recited symbol so defined, therefore the prior art does not provide support for applicants' argument. Thus, the rejection is maintained for the reasons stated above and in the previous office action.

### ***Claim Rejections - 35 USC § 103***

Claims 21-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Alon, *PNAS*, 96:6745-6750 (1999), in view of Lazaridis, E., Discrimination and classification using conditionally independent marginal mixtures, *A Dissertation Thesis*, Chicago, The University of Chicago, Illinois, December 1994, and further in view of Skene, *Statistics in Medicine*, 11:2111-2122 (1992).

Applicants argue that Alon does not identify latent classes of genes from a matrix in a first direction, latent classes of cells from a matrix in a second direction, and calculating the likelihood that each gene is a member of each latent class. Applicants do not address the

Art Unit: 1631

rejection based on the combination of Alon, Lazaridis, and Skene. Applicants' arguments have been considered, but are found not persuasive.

Applicants are reminded that the rejection is made under 35 U.S.C. 103(a) over a combination of references.

In response to the argument, it is noted that although that Alon does not disclose latent classes and a formula as recited in instant claim 21, Alon discloses calculating the probability that each gene and cell is a member of a certain cluster (p. 6746, right col.; for cell-line cluster, *see* p. 6749, left col.). Lazaridis discloses a latent class formula similar to that of the instant claims (p. 7, expression 1.2.1, p. 9, expression 1.2.3) and calculating a likelihood that an object belongs to a subset of a particular characteristic (for example, p. 37 and p. 78), and Skene discloses parameters of the response, *i.e.*,  $(\mu_{jm}, \delta_{il}, p_{ij}, \sigma^2)$  (p. 2114), as set forth in the previous office action.

Motivation to combine the references was presented in the previous office action and is reiterated below:

"It would have been obvious to one skilled in the art at the time of the invention to modify the method of Alon to apply a latent class model for analysis of biological data, such as taught by Lazaridis and Skene, where the motivation would have been to improve correlation of data obtained from an object and an attribute, as taught by Lazaridis (Abstract, p. xi) and Skene, p. 2120."

For the reasons stated above and in the previous office action, the rejection over the combination of references by Alon, Lazaridis, and Skene is maintained.

***Conclusion***

No claims are allowed.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marina Miller whose telephone number is (571)272-6101. The examiner can normally be reached on 8-5, M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel, Ph. D. can be reached on (571)272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1631

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Marina Miller  
Examiner  
Art Unit 1631

**MARJORIE A. MORAN**  
**PRIMARY EXAMINER**

MM

*Marjorie A. Moran*  
*2/16/06*